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EXAMINER

DAVIS, KATHARINE F

ART UNIT

PAPER NUMBER

1636

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/705,940

Applicant(s)

FIKE, RICHARD M.

Examiner

Katharine F. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 17, 30 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15, 16, 18-29, 31-34 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This Office Action is in response to the application filed on November 6, 2000 and to the Reply to Restriction Requirement filed on March 26, 2002. Claims 1-39 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I (1-10, 15, 16, 18-29, 31-34 and 36-39) in Paper No. 4 is acknowledged. The traversal is on the ground(s) of Applicants' assertion that there is no burden of search placed on the Examiner to search Groups I, II and III because all three groups are classified in the same class and subclass. Applicants further assert that the electronic search of both patent and non-patent databases for each Group would not place on undue burden on the Examiner.

To establish that a search would present an undue burden, the examiner must show that the restricted groups have a separate classification, have acquired a separate status in the art, or that searching would require different fields of search. MPEP 808.02. The examiner is only required to show one of these three criteria to establish that restriction based upon an undue search burden is proper. Groups I-III are each drawn to patentably distinct methods for cultivating a cell, each method requiring different steps. A search (both patent and non-patent) would require a search for all three methods underscoring the fact that the searches for all three groups are not coextensive. The distinct steps of each method would a search using additional search terms that would result in more hits for consideration. Both the extra terms and hits to consider which would be required to search all of the pending claims results in a larger and thus more burdensome search for the examiner as compared to the search that would be required for

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one group. The requirement of separate (or additional) search terms for each constitutes a separate search requirement for each group thus establishing that searching requires different fields of search. Thus, Applicants' argument is not found to be persuasive. The requirement is still deemed proper and is therefore made FINAL.

Claims 11-14, 17, 30 and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4. It is noted that claims 18, 20, 32 and 36 will only be examined as they read on the elected subject matter of Group I.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

Reference AR6 of the IDS filed on June 14, 2002 has been considered, however the portion referring to the web page address has been deleted from the citation as the IDS references would be printed in any patent that will issue from the instant application. Hyperlinks and other forms of browser-executable codes are not permitted. See MPEP 608.01.

Specification

The disclosure is objected to because of the following informalities:

In the Brief Description of the Drawings section each panel or drawing containing multiple panels must be referred to as a separate figure. The first line of each description must refer to each separate figure, for example, page 11, line 2, of the instant specification should read Figures 1A-1B. Appropriate correction is required for figures 1-9, 11, 12, 16, 17 and 19.

At page 41, line 25, of the instant specification the city/state location of the American Type Culture Collection should be updated.

Claim Objections

Claims 4, 15, 18, 20, 32 and 36 are objected to because of the following informalities: Claim 4 appears to be missing “is” between the terms “sterilization” and “accomplished”. Claim 15 appears to be missing “of” between the terms “method” and “any” in line 3. Claims 18, 20, 32 and 36 are dependent from claims not elected for prosecution in the instant application. Appropriate correction is required for claims 4, 15, 18, 20, 32 and 36.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 15, 16, 18-29, 31-34 and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incomplete. There is no positive process step which clearly refers back to the preamble.

Claims 2-4 and 9 recite the phrase “dry powdered medium”. There is insufficient antecedent basis for this phrase in the claims. This rejection may be overcome by amending the claims to recite “dry powdered **culture** medium”.

Claims 5-7 are indefinite in that they fail to point out what is included or excluded by the claim language in the use of the “and/or” terminology. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 15, 16, 18, 19, 28, 29, 31-33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,773,279 (Miller *et al.*) as evidenced by Brock *et al.* (Biology of Microorganisms, Fourth Edition, Prentice-Hall, Inc., section 8.4, page 257, 1984). Miller *et al.*

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teach a method for producing a dry powdered culture medium comprising opposing buffer salts (see throughout and especially Table 1). The buffering salts of Miller *et al.* are monobasic potassium phosphate and dibasic sodium phosphate (see Table 1). Miller *et al.* additionally teach a method for cultivating a bacterial cell comprising reconstituting the medium with a solvent (water) to form a culture medium solution and contacting the cell with said solution under conditions favoring cultivation of the cell (see column 2). The cultured cells in the medium of Miller *et al.* comprise a composition. The medium of Miller *et al.* comprises a lipid (chicken fat, see column 3) and Miller *et al.* further teaches packaging and sterilization of their medium (see objects, column 3, line 32 and column 4, line 2). Kits comprising the medium of Miller *et al.* are also disclosed (see column 4). Miller *et al.* does not specifically state that their medium is automatically pH-adjusting however they give no indication that any pH adjusting agents are added to their medium after the buffering salts. One of skill in the art reading the methods of Miller *et al.* would realize that the use of buffering salts is for the purpose of maintaining the correct pH for cell culture, as evidenced by Brock *et al.* a textbook dated 1984, sixteen years before Applicants' filing date. It is noted that claim 10 is a product by process claim and thus the process must confer a patentable distinction upon the product. Absent evidence to the contrary it would not be possible for one of skill in the art to distinguish between the claimed culture media and the media of Miller *et al.* Claims 1-3, 5-8, 10, 15, 16, 18, 19, 28, 29, 31-33 and 36 read on the methods, medium, kits and compositions of Miller *et al.*

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,773,279 (Miller *et al.*) in view of the GibcoBRL Product Catalogue and Reference Guide 1995-1996 (IDS reference). Miller *et al.* is applied as above in the 102 rejection section however Miller *et al.* does not specifically disclose that their cell culture media formulation can be used to culture eukaryotic cells such as, yeast, plant, mammalian (human and animal) and cell lines derived therefrom. The GibcoBRL catalogue discloses several commercially available media for eukaryotic cells and cell lines, for example, Gamborg's media (plants), McCoy's (human) and D-MEM (mammalian cell lines). The pH of these media preparations must be properly adjusted before the cells are added. The methods and media of Miller *et al.* were known in the art at the time that the instant invention was made and further the media formulations of GibcoBRL were

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commercially available for purchase at the time that the instant invention was made. One of ordinary skill in the art would be familiar with them. One of ordinary skill in the art would also realize that adjusting the pH of media involves time consuming steps in media preparation bringing additional opportunities for contamination of the media potentially requiring extra sterilization and more time consuming steps. One of ordinary skill in the art would be motivated to add the buffering salts as taught by Miller *et al.* to any of the media disclosed in the GibcoBRL catalogue to eliminate the pH adjusting step of media preparation therefore arriving at the instant invention and thus rendering the instant invention as claimed in claims 20-27 obvious. Given the teachings of the cited prior art and given the level of skill of the ordinary artisan practicing cell culture techniques at the time that the instant invention was made, said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,773,279 (Miller *et al.*) in view of US 5,155,039 (Chrisope *et al.*) Miller *et al.* is applied as above in the 102 rejection section however Miller *et al.* does not specifically disclose a composition comprising a dry powder medium and at least one cell. Chrisope *et al.* disclose a kit comprising dried viable microorganisms stored in a vial (see abstract). The media disclosed by Miller *et al.* is conveniently stored in a powder form, easily sterilized, and convenient to use since the addition of buffering salts eliminates the need for pH adjustment. The cells of Chrisope *et al.* are stored in a dry form and ready for use. Both the method of Miller *et al.* and the cells of Chrisope *et al.* were known in the art at the time that the instant invention was made. Combination of the

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cells of Chrisope *et al.* with the media of Miller *et al.* would reduce storage space by elimination of storage vials and additionally eliminate steps in the preparation of bacterial cell cultures. One of ordinary skill in the art at the time that the instant invention was made would have been motivated to combine the cells of Chrisope *et al.* with the media of Miller *et al.* to produce a composition of powdered media and cells which can be easily reconstituted by addition of a solvent therefore arriving at the instant invention and thus rendering the instant invention as claimed in claim 34 obvious. Given the teachings of the cited prior art and given the level of skill of the ordinary artisan practicing cell culture techniques at the time that the instant invention was made, said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

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Conclusion

Claims 1-10,15, 16, 18-29, 31-34 and 36-39 are rejected. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry of a general nature or any inquiry concerning the formalities of this application should be directed to Patent Analyst Tracey Johnson whose telephone number is (703) 305-2982.

Katharine F. Davis
June 14, 2002


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